SBIR Contract Topics Webinar Transcript

Jennifer Shieh: Green bar at the top of the screen that says SBIR application and click the Q&A box or the drop down menu box. And as a reminder, so all of you are currently muted and you will need to submit your questions in the Q&A box. Please submit questions that are of a more general nature of the context topics or context process and not submit any proprietary information as we will be recording the audio, the slides and the Q&A and we will be publishing it to the website. So if you do send any questions that are specific to your project, we won't be answering them. If you have specific questions about your project you should send them if they're about contacts to Elizabeth Shanahan or if they're about grants you can send them to ncisbir@mail.nih.gov.

And so now I'll hand it off to Michael Weingarten, the director of the NCI SBIR development center to do an overview of the program.

Michael Weingarten: Thank you very much. I want to thank everybody for joining us today. The reason that we wanted to hold this webinar is to give you an overview of the NCI SBIR program as a whole which I'll be going for forty minutes and I'm also going to focus on what it takes to get funded provide some tips to applying and also just walk through the contract process at the NCI as a whole. Following my presentation, we'll have about ten minutes for Q&A which will be based on the questions that you send in through the Q&A box that Jennifer mentioned a minute ago. And then we'll go into some of the specific funding opportunities that are currently available that Andy Kurtz and Deepa Narayanan are going to be presenting on specific contracts and funding opportunities and giving you the details on those and then we'll have some additional time for questions an answer after that. So again, feel free to ask questions as we're going through the presentation and we'll do our best to get through as many questions as possible. If you have a question about your specific project, again, I encourage you to—again if it's a grant if it's a contract question please send an e-mail to Betty Shanahan and her contact information was in the slide and we'll show that again. And if you have a grants question you can send it to the general NCI SBIR mailbox.

So why don't we go ahead and get started. Why don't I just give you a brief overview of the SBIR program as a whole. So SBIR and its sister program, STTR program are government set aside programs and one of the nice things about the program is when it was reauthorized almost two years ago, congress set an increase to the set aside amount for this program over the next five to six years. So if you can see this year starting in fiscal year 14, the set aside amount is 2.8% of the NCI budget for SBIR and .4% for the STTR program. On an annual basis our budget at the NCI is about $110 million between both programs. And just a little bit of background information. SBIR is a set aside program specifically for small businesses engaged in federal R&D and it's the largest of the two programs where as the Small Business Technology Transfer Program—the goal there is to spin out technology from typically from a university to a small business and then to commercialize that technology. Let me go to the next slide here.

Why should you, as a small business be interested in seeking SBIR funding? Well, there's a number of reasons. First of all, it's funny, the largest source of early stage seed funding for technology development and certainly in the life sciences world now. It's not a loan. There's no repayment required. And as such it's non-dilutive. It doesn't impact the stock or your shares in the company in any way. The other couple of reasons ear that the intellectual property rights are retained by the small business and because you go through the peer review process at the

NIH in terms of review of your application, if we do decide to fund your company and fund your project that helps provide recognition and verification about the viability of your idea which can help you in terms of trying to go out and raise additional funds from either venture capital, angel investors or from strategic partners like big pharmacy.

So SBIR and STTR are three phased programs. Phase one is a feasibility study and typically it's about those average in terms of dollar size about $50,000 over six months for an SBIR or one year for an STTR but we do have flexibility to fund projects up t o$225,000 for phase one projects.

For phase two, that's the full research and development of the technology, typically it's a two to three year project and commercialization strategy is a critical part of your application. We can fund projects up to one and a half million projects for phase two awards but there are caps now with one of the things that Congress did do was put caps on award sizes for phase one and phase two. $225,000 for phase one and $1.5 million for a phase two.

Phase three is the commercialization of the technology and you're supposed to use non-SBIR and STTR funds in order to move it towards commercialization. We launched a program here oh, actually—let me go back before we go to the next slide.

There is a nice option we also have at the NIH. We call it a fast track application where you have the ability to submit both a combined phase one and phase two application. The benefit of doing so is that you go through one review process for both your phase one and phase two. However we encourage companies to only come in with a fast track application if you have a lot of primarily data because review knows that they're only going to see it once so in order for them to score your proposal well, they're going to want to see a lot of preliminary data as part of the proposal. So that's something to consider in terms of which route you go.

We launched a program here at the NCI that we call our bridge award program about five years ago now and this is actually a program that fits in between phase two and the commercialization phase. And it's strictly to help those companies that have promising progress on their projects over the phase one and phase two periods but they need additional funding in order often times to take a therapeutic or a device into the clinic. We provide the opportunity for companies that have received phase one and phase two awards to apply for a bridge award which is up to $1 million per year for up to three years over the course of an award and the goal again is to really help companies get over the valley of death and to also help them raise additional funds from third part investors.

One of the aspects of the bridge award program and the expectation is that when you apply for one of these awards is that you're going to be able to go out and raise substantial third party funds from other inventors and our expectation is that if you're going to request up to $3 million from the NCI under this program than you would have raised a commitment from others to provide at least $3 million in funding for this particular project.

As to eligibility requirements a little bit different between SBIR and STTR. I'm going to review SBIR first. So first the applicant has to be a small business concern. You have to be organized for profit here in the United States and you have to have 500 or fewer employees including affiliates. The other requirement for SBIR is that the principle investigators primary employment must be with the small business concern at the time of the award and also for the duration of the project. So that means you've got to be over 50% of your time has to be with a small business concern.

The other key requirement is that you've got to have your ownership has to be either 50% US owned by individuals and independently operated or 50% owned and controlled by other business concerns that are 50% owned and controlled by one or more individuals.

One of the recent changes in the program that congress made is that we are now allowed to fund companies that are majority owned by venture capital operating companies. So that rule just came into effect in August of this year and the rule states that you can be majority owned by either multiple venture capital operating companies, hedge funds or private equity firms or any combination of those above.

For STTR, the again, the applicant has to be a small business concord, but the goal of the program, since the goal is to get technology out from US research institution to a small business, here has to be a formal cooperative R&D effort so you have to have at least 40% of the work done by the small business owner in STTR proposal, but also at least 30% done by a US research institution. So a US research institution could be a college or university, could be a non-profit research organization or it could also be a federally funded R&D center.

One of the attractive aspects of the STTR is that the PI's primary employment can be either with the small business concern or with the research institution, so you can stay, if you're at a university and you want to continue to pursue the project, you can do that without having to leave and join the small business. The other key requirement is you're the small business concern must have the right to—there must be a negotiated intellectual property between the small business concern and the US research institution so that the small business has IT rights on the technology being developed.

We would encourage you to take a good hard look at the STTR program as one of the notions if reconsidering applying. We are encouraging and trying to get more applicants under this program and you know we think it's a good opportunity for you.

The difference between SBIR and STTR. SBIR permits partnering arrangements between a small business and other parties including universities, but it doesn't require. STTR does require it. And I went over the strict requirement. So if you still want to come in under the SBIR program and partner with a university you can do that, but 67% of the dollars has to go to the small business that which still leaves a third that could be contracted out and this is under phase one. For a phase two 50% of the dollars still has to stay with the small business whereas 50% can be contracted out.

The other key requirement is that the PI the primary employment must be with the small business under SBIR whereas under STTR it can either be with the small business or with the university. In both cases the small business has to be the actual applicant on the project.

We move on to talk about the programs as a whole at the NIH. So NIH has a total of twenty seven different institutes and centers and those are listed here on this chart. NCI is the largest institute out of the twenty seven and we represent about 18% of the overall NIH budget which also means that we represent 18% of the overall SBIR budget at the NIH.

So there are multiple funding solicitations that NIH puts out for you as a small business to apply to. The one many of you might be familiar with is what is known as the SBIR and STTR Omnibus Grant solicitation that comes out in January of every year with three different receipt dates and those are in April, in August and also in December. We also come out with more targeted program funding analysis announcements that are released throughout the year and those are either program announcements or requests for applications or RSAs. And what we're really going to be focusing on today is SBIR contract solicitation that was released in August and again has a receipt date of November the 25th. For contracts in particular and only for contracts

you are required to submit a paper contract submission as opposed to submitting your application online. So that that's an important consideration particularly in terms of the deadlines that you're shooting for. You have to account for the time to actually send you proposal in for us to receive it.

So if you are interested in getting more information on the different funding solicitations that NCI offers, I encourage you to go on our website which is SBIR.cancer.gov and you can link to funding opportunities which the arrow points to here from our website. You can also get some additional information about the program and you can sign up for updates which you see towards the bottom of this box here. If you sign up for updates, you can just give us your e-mail contact information and whenever we come out with a new funding opportunity, if we're launching a new program under NCI SBIR then you would automatically get information about that. We encourage you to go up on our website and really sign up for these updates that you can keep up to speed on the latest developments of the funding and the latest funding opportunities.

So I'll talk just a few minutes about our program at the NCI—we're a little bit different at the NIH in that we've set up a center for managing this program. We launched our center about five years ago and these are the—what you can see in the slide is that these are the members of our team and if you can see we've hired program directors to manage the program. Most of them come to us with strong industry backgrounds and also with technology backgrounder they focus nonspecific areas. So if you have a project idea that involves—you can actually pick the program director that matches your project area and reach out to us and one of our folks would follow up with you. This would be in the grants arena specifically.

To give you a sense of how we're spending our funds at the NCI in terms of what our portfolio looks like, about a third of our portfolio is invested in therapeutics project, about 20% in diagnostic, 20% in imaging and about 12% in healthcare IT an software tools. It really is a broad based portfolio that cuts across the cancer space as a whole.

Just a little bit f information on some of the programs that we offer to both our grantees and the contractors that we select and that are getting funded by our program. One of the things that we hold on about every year and a half or so is our NCI SBIR investor forums and what we do is we go through our entire portfolio of projects and we identify the most promising fifteen to twenty companies that we're funding and we put on an investor forum to help showcase our top companies and introduce them to investors and help them form strategic partnerships or collaborations. It's specifically beneficial as companies are graduating from the SBIR program and they're looking to raise additional funding. So we've actually held our investor forum three different times. When we held this event back in 2010 we showcased a total of fourteen different companies and coming out of that event, actual eight of the fourteen presented companies were able to close deals and raise funds collective valued at over $230 million. So you know we're not just trying to provide funding from the NCI but we work very closely with the companies that we fund to help you achieve success and to help connect you with potential partners or investors.

Another thin that we do, we actually launched this for the very first time this year is we put on a workshop on federal resources that are available to help your company as you're moving towards commercialization. So the very first time we held this was back in May of this year and we invited all the companies that we were funding under our program and they were able to hear and presentations and also meet with representatives from the FDA, from CMS and from the patent and trademark office and from other federal agencies and our goal here was to educate to you about programs that other government agencies are offering so that you can tap into them and also just get their advice because often times with the FDA that can be very helpful. We're

just trying to make you aware of other resources that are available to your company as you're developing your technology and moving it into the clinic.

At these same meetings we also offered the opportunity to meet with us one on one as well as the other agencies that are participating. I'm going to just go into a little bit onto the tips for how to submit your proposal. This gives you a sense of the contract proposal process. Typically the solicitation is in August and then you have the receipt date—the due date for applications is November the 25th. We have to have your paper application received for the contract solicitation on November the 25th at 4:30. That means we have to have it in our hands by that date. Following receipt of your proposal the NCI will form different study sections and review panels and conduct the reviews of proposals. They take place in the January to April time frame and by the June to July time frame you will receive a notice from our contracts office that will tell you whether the NCI would like to proceed forward with negotiations on your particular project. So that will be either, yes, we do want to proceed or no, you know because of the competition and involved in the application, we are not going to proceed. And for those that are denied going forward, you will actually get the technical evaluation minutes from the review panel that will tell you about the strengths and the weaknesses of your proposal which you can then use in the future.

And then, the negotiation process beings at that point for those who received a yes and that –negotiations go forward between July and September and awards are typically made in September of every year.

The most important thing that you need to do is look at the solicitation because it really walks through all the different details that you need to be aware of when you're putting together your application. Most of your questions would likely be answered within the solicitation itself, and so this provides the link to the actual contract solicitation and we just—and released an amendment to the contract solicitations. This provides a link to that. That has the new deadline which again is November the 25th and I believe we also had an amendment to one of the contract topics which Deepa will speak about in her presentation.

In terms of deciding to submit a proposal. Are you a good fit for the contract topics or not. Our suggestions are that you look at some of these key points, but the first is does your project fit the contract topic description fairly well. Is it a nice fit for the goals or the contract topic and the expected milestones and deliverable, because unlike a grant, under contacts we do have specific milestones you have to achieve and specific deliverable that you're expected to achieve by the end of the contract. The other key is you have an innovative solution to a significant unmet clinical need. Do you have significant commercial potential, a particularly under the SBIR program as a whole, this is not a research project that we expect you're going to be developing a technology that ultimately we're going to look to you to commercialize and get out to patients. Commercial potential is going to be one of the key criteria and the review and selection of your award.

Do you have the right type of expertise and background in the given area that we're looking for and under the contract topic and can the funding be used to produce feasibility data on the specific project. Start ups—we start ups represent a large percentage of ht projects that we fund. SBIR can be an excellent vehicle for you to apply for and receive funding under. Oftentimes start ups can have difficulty getting additional funds.

When not to submit a proposal? Well, we don't recommend submitting a proposal is you're just trying to—if you need cash and you're trying to raise cash but you don't have a particular expertise in the areas that we're looking to receive proposals in. The other reason not

to submit is if you just have an incremental upgrade to an existing technology but you're not looking to provide a change to a critical paradigm to the technology area. Or if you just have a "me too" product that matches you're competitors' capabilities. If you're going to apply for SBIR we want to see a significant improvement in terms of the state of the art in terms of the technology that you developing. Another reason not to submit is if it's just a basic research project or there's a lot of basic research that needs to be done to demonstrate the feasibility of the technology.

So two tips for submitting your proposals start when the solicitation is released so again, read the solicitation carefully. Other things there are certain administrative registrations that you need to do as part of your submission so that includes a Dunn and Bradstreet registration as well as registering on SAM.gov and also going to the SBIR.gov SBA company registry site and registering there. All these are described in the actual contract solicitation document so the details on exactly what you need to do there are in the solicitation.

Two tips for submitting a proposal are to build the right team, to partner to fill the gaps. We understand that you're a small business and you probably don't have all the capabilities that you need in house to accomplish the goals of the project but you can partner with others, maybe other companies or potentially with academic to help fill those gaps. They can be consultants or contractors on the contract you're submitting.

The other thing that will help your application is if you get letters of support both from your partners but also from potential customers of your technology. If—for example, you're able to submit a letter of support from a potential customer, that helps validate that there's an interesting and a need for the technology that you're going to be developing and the ultimate product that would be coming out of that.

The other things to note are that to think about the reviewers that are going to be reviewing your proposal so the reviewers only see the proposal itself. You need to talk about how the proposal fits within the goals of the contract topic itself and in the milestones for that topic. What is the problem that you are uniquely able to solve under your proposal and why is it your approach that you're proposing, why is it innovative, again innovation is one of the key review criteria and what is the potential for commercialization. We also encourage you to help form your own peer reviews, so collect a set of your colleague to read the material critically as if they were the reviewers themselves and ask your collaborators to also review the proposal and they can give you constructive feedback that you can use to enhance the proposal before you submit it.

The other thing that you can do—we oftentimes get questions from potential applicants on is this an area that the NCI is going to be interested in. so one of the things you can do is you can go up on a database and it's called NIH project reporter. We give you the website here and you can actually run a search on a particular technology area that you're interested in proposing in and you can actually look to see if NCI has funded projects in that area before. And if we have funded projects in that area, that might give you an indication that we're likely to have an interest in that area.

So again, for questions, regarding contracts, I encourage you to submit those to Elizabeth Shanahan and this is her e-mail. For grants if you're questions are grants related you can actual contact us directly in the SBIR office and you can speak with a program director. Probably the best way to get that whole process started is just to go to our e-mail box which is in NCISBIR.mail—-SCISBIR@mail.NIH.gov. We encourage you to contact at least one month

before the due date for the particular solicitation so that we have time to give you some feedback and you have time to incorporate that feedback as part of your application.

This just gives you a snapshot of what project reporter looks like and some of the key search terms that you should consider. If you're trying to look at other projects we might be funding. So let me briefly run through the contracts process at the NCI and I'll close on that and then we'll be open up for questions from the audience.

So contracts are different from grants in that NCI every year we put a lot of thought into identifying certain technology areas that are high priorities in the NCI and that we feel that the NCI-SBIR program is actually a good vehicle for moving those particular topic areas forward. So we're looking to seed investments in each of these areas and all of these areas we do a fair amount of research before we announce them to the public where we identify the scientific potential and we identity it as a priority for the NCI, but we've also looked at the commercial potential in the given area to make sure it's appropriate to the SBIR program. Topics really reflect that and as you can see contracts represent an important percentage of our budget for the NCI SBIR programs at the NCI. Just this past year, we invested about 35% of our overall SBIR budget into contracts.

But what are some of the differences sweeten grants and contracts. In terms of the scope grants are investigator initiated and again if you are familiar with the program again we come out with the omnibus solicitation and we're under the bombings grant solicitation we're looking for you to bring us your best ideas on technologies that you're developing that you want to move forward into the clinic and ultimately towards commercialization.

Under contracts NCI is actually defining the topic area and these are much narrower in focus than you'll see in the grant side. In terms of questions during the solicitation period for grants, yo can contact us directly and speech with any program officer in the NCI SBIR office. For contracts you need to contact the contracting officer and again that's Elizabeth Shanahan.

Receipt dates. We have the omnibus comes out at the beginning of every year, again in January. With three different receipt dates. For contracts there's the contract solicitation comes out in August and it only has one receipt date during the year. The reporting requirements are also very different. Under grants you for a phase one you only have one final report that you ambit whereas under phase two you submit annual reports. Under contracts you're a lot more involved in working with your project officer at the NCI. We expect at the beginning of the project you'll have a kick representation where you'll work with your project officer as well as the contracting officer in taking off the project. And then following that we get quarterly progress reports on how you're progressing in terms of your milestones which are really important under contract and then we also get a final report at the end of either your final phase one or your phase two and we also get a commercialization plan as part of your project.

The other two differences, under contracts we do have set aside funds where we identify for each contract topic how much we would like to invest in that particular topic anyhow many awards we would like to make. For grants we don't have a specific set aside fund.

The review is differential under contracts versus grants. So if it's a grant application typically your proposal will go for the NIH—will go the NIH center for scientific review or CSR and they will form a broad based study section where your application will be reviewed. For contracts, again these are very focused topic areas so they're actually reviewed at the NCI by our division of extramural activities and the form very specific review groups for each individual topic. Again, very different in the way the reviews are done.

The basis for the award. Your peer review score is going to be critical in both cases between grants r contracts but part of the contracts process is once we make a decision that we're interested in your project, on the contract side we go to a negotiation prospect where we expect certain technical deliverable and those technical deliverable come out of the process. That will be a key part and a process before an award is made. That is not done on a grant side.

In terms of fast track which are combined phase one/phase two applications, on the grant side, phase one and phase two are considered as a single application with a single score, but under contracts phase one and phase two are considered separate proposals so they can be reviewed an scored independently.

This gives you an overview of the technical evaluation criteria that are used in contract reviews, specifically focuses on phase one and this is really another important difference between grants and contracts where we assign a weighting to the different review criteria. That is, again, not done on the grant side. You don't have a weighting of the different criteria. As you can see soundness and technical merit are weighted at 40%. The qualification of the proposed principle investigator is at 20%. The technological and the innovation of your proposal is at 50%. And if you can see the potential for proposed research to commercial application that's actually broken out into separate weighting criteria in terms of what it's commercial potential is, but that's weighted at 15% for phase one, and finally the adequacy and suitability for your facilities are at 10%.

For phase two, criteria weighting is different. Technical merit 30%. Strengths of your proposal in terms of its commercial potential and the strength of your commercialization strategy that's 30%. Qualification of proposed principle investigators 25%. And the adequacy of faculties at 15%.

Now we are at the Q&A phase and we'll open it up to questions.

Jennifer: Great. Thank you very much. And I will get started with a few of the genera questions that have been coming in. So for example, one question that came in was how much preliminary data is required? And Michael—?

Andy Kurtz: This is Andy Kurtz. I'm one of the program directors here at the center. There actually is no requirement that you include any data or an SBIR phase one grant application or contract proposal. I will say, though, that competitive applications almost always do include a substantial amount of preliminary data. Remember that we're living in a very competitive funding environment right now so I would say not to consider submitting a proposal unless you had at least some preliminary data too that establishes the foundation for what you're proposing to study.

Jennifer: And another question about what goes into a proposal, how do you describe commercial potential? What is being looked for and what is defined as commercial potential?

Andy: This is Andy Kurtz again, I think it depends on the technology or some technologies for example in the area of drug development it's appreciated that they're going to be very large after requirements and time frames for the ultimate marketing and regulatory approval of a new therapeutic. In that scenario what we would look for in terms of commercial potential are things like is there a reasonable plan in place to secure the appropriate folks that can provide regulatory guidance. Is there an appropriate preclinical development plan in place to introduce critical

milestones and key inflection points that would then bring investors to the table to fund the next stage of development. The contract that with another technology, for example are research tools for which there may be no regulatory paths, we would have expectations that your plan be much more specific in terms of thing like manufacturing and have you talk to customers, do you understand what some of the competing products look like and how yours could be differentiated and what would be your actual strategy for beginning your product to market. So again, to emphasize for contracts, we're not at liberty to have in depth conversations about this issue but certainly on the grant side, you're encouraged to contact the program director and have a discussion about your technology and what we might look for.

Jennifer: So another—some questions about review. So do the reviewers of grants and contracts have similar backgrounds?

Michael: Well, yes. They do. Typically in the SBIR study section you have a combination of both academic and commercial reviewers, so people with industry backgrounds and academic background so depending on the study section you were assigned to you know those backgrounds will vary based on the topic that' being reviewed. For contract topics those reviews are very focused so that we work very closely with our review decision at the NCI and recommending reviewers that are well suited for the particular contract topic, so typically you cover the science very well, but you also include people who understand the commercial space around the given area very well, so that they have the right kinds of backgrounds to know whether the company and the proposals are being reviewed, whether they have the ability to achieve commercialization.

Jennifer: So there's a quick question of can I do an electronic submission. The answer is no. All paper. For contracts. That's for contracts.

And—another question quick question is whether somebody can propose a budget that is greater than is listed on the topic, and kind of a related question on this discussion of what the phase one budget generally would be like a minimum or maximum—

Betty Shanahan: This is Betty—You have to look at the solicitation section twelve is a description of this topic and the dollar value for the phase one where if it's a fast track phase two it's broken down. It's specified. I also see somebody has a question about a percentage for the number of awards. Identify a percentage at a number of awards is a glance or function. What you'll see again when you look at section twelve of the solicitation under each topic we identify the anticipated number of awards. That's really the best. We can't say what the percentage is because we don't know how many proposals we're going to receive and under each topic we don't know how many are going to get through review. Last year we had a topic where it got two proposals and neither one of them got through, so that whole—the percentage in the case of a contract topic is not a good indicator. The best indication is the number of awards that are anticipated.

Jennifer: I think this is another common question about the pros and cons of submitting a fast track versus delaying a phase two submission for a contract proposal, which is only applying for phase one versus applying for the fast track for a contract proposal.

Andy: Just to reiterate something Michael said and explain some of the implications of some of the differences between grants and contracts. When you submit a fast track contract the phase one proposal and the phase two proposal are scored independently. For a grant they're scored as a single package, so you get one score for both proposals. The implications for contracts for those being scored independently, one indication is that if the phase one scores particularly well but the reviewer thinks that there's still quite a bit of risk associated with the phase one activities, such that the phase two proposal doesn't score well, we have the option to decide only to fund a phase one proposal, which is a benefit for you as an applicant. Again with grants if you submitted a fast track grant and the phase one scored well or the phase one portion generates a lot of enthusiasm but the phase two does not, then that phase two section can drag down your total score and leading to nothing getting funded.

I think in all cases, though, the biggest consideration on whether or not to submit a fast track really is the amount of preliminary data that you can point to that suggests a low or relatively low level of technical risk for the phase one portion of the study. If you put yourself in the mind of a reviewer they're looking forward to the phase two work plan and if there's still too much risk and too many unanswered questions based on the phase one work, then it becomes very hard to see how you can be comfortable going forward with the whole fast track project without getting some early data.

Betty: This is Betty. I want to add that if you're successful with a phase one award that's not the only opportunity to get a phase two award, from this source. Everybody that gets a phase one can compete for a phase two award. It used to be by imitation only. That's not the case. If you're successful in receiving a phase one award, you can compete for a phase two award.

Todd Haim: In terms of time line it usually historically can take about a year in between the end of your phase one and the beginning and getting awarded a phase two and this is assuming you're not going a fast track so typically your phase one may end around June of one year and it's usually something like August or September of the following year that you would get awarded a phase two. Just to give you a sense of kind of a time line.

Jennifer: I think we probably need to move on to talking about the specific FY14 funding opportunities now, but we will have time at the end to go back to some more Q&A. So now introduce Dr. Andrew Kurtz who's a programming director.

Andy: Thanks, Jennifer. So what we'd like to do in the next few minutes is just take you relative quickly through the eight specific contract topics that are currently being solicited. I'll try to point out a couple of specifics in each of those topic write-up to try to highlight some of the questions that came up on the other things that Michael presented early on. So we moved along to the slide that is entitled Topic 326, development of novel therapeutic agents that target cancer stem cells.

Now—bear with us while we get to the slide. And now we're at that slide. Okay. So again one of the first things you should look for is the levels, the budget levels that are listed for each topic. They are not necessarily the same as statutory guidelines for grants. You should look at the specific budgets that are associated with each topic.

For this first topic, 326 the phase one level is $225,000 and future phase two proposal could be for up to $1.5 million. Again, we talked a minute ago about the fact that each topic list

a number of anticipated awards. That really is contingent upon receiving a significant number of meritorious proposals, so for example under this topic, if we only receive five, and they were all poor, then we could fund zero. Typically we would not go above the maximum number that's published, so that gives you some sense of how many you can expect that NCI would support in the best case scenario.

We were just talking about fast track proposals. Each contract topic will list at the very top whether or not fast track proposals will or will not be accepted. This topic is the only one in this year's cohort for which we will not accept fast track proposals, so again you can submit a phase one for up to $225,000. the phase two proposal would be something that you would submit in response to a future invitation.

So the goal for this topic is fairly straightforward. It's to develop novel therapeutic agents that target cancer stem cells, in particular cancer stem cell related bio markers or cancer stem cell related pathways molecules that effect fundamental processes associated with parthenogenesis, tumor progression, recurrence or metastasis.

Something I would note for each of the contract topics, typically they will provide some information about the expected starting point. So for example, this target—this topic has the expectation that you're beginning for the point of having at least one validated target from the cancer stem cells that are delivered from your cancer indication that you're going to study. There's more information in the topic about those other prerequisites but you should read those carefully so that you know where the expectation is as far as the starting point.

The remaining information on this slide tells you about the phase one activities and expected deliverable. Again, just to reinforce something that Michael just told you, the quality of your proposal is going to be judged against how well it addresses these specific activities and deliverable that are listed in the topic. So you should read these very carefully and make sure that your proposal addresses the key requirements that are being asked for. In this case, we are looking for you to demonstrate future efficacy of the agent or agents that target the cancer stem cells, to validate the effect of those agents and to conduct structural activity relationships study, med chem and or lead antibody optimization as appropriate for your lead and to perform animal to and pharmacology as appropriate for the agents and the not develop a detailed experimental development plan that you would pursue under a phase two award, ultimately to filing an R&D or an exploratory R&D.

Moving on to the next topic. So this one is topic 327 entitled reformulation of chemotherapeutic drugs. Our goal here is to add new agents to our current goal of chemotherapeutic drugs by identifying and evaluating some new delivery systems that can enable the use of drugs that are otherwise not able to be delivered to humans in their free form. In particular, this topic is focus don reformulating small molecule chemotherapeutic agents that have failed previously either in preclinical development or in human clinical trials.

In this topic, we actually call out specific activity that would not be accepted under this topic, for example, any chemical entity that's received FDA approval for any other indication whether right's cancer or otherwise would not be acceptable for development under this topic. In addition we would not consider responsive if you simply propose to do—to chemically modify a failed chemotherapeutic agent. That is saying to do traditional med chem on an agent that was previously found not to be efficacious.

Under this topic, under phase one deliverable and activities you are expected to identity an appropriate cancer indication for the proposed reformulated drug and to demonstrate proof of concept that you can either attach or encapsulate or otherwise incorporate your candidate

chemotherapeutic agent into your novel delivery system and the not conduct proof of concept small animal studies in therapeutic efficacy and whatever other improved properties over the drug that you're proposing to improve.

I would also again point you to some additional requirements in this RFP about the expectation that you as the offered are expected to identify the chemotherapeutic agent that you're going to study. The NCI is not going to provide any list of compounds for that particular topic.

The next topic is topic 328 entitled validation of human tissue culture systems that mimic the tumor micro environment. So this topic is in recognition of what's been accepted as a need to improve the accuracy of preclinical drug efficacy screening and testing through development of new in vitro culture systems that can more effective mimic the in vivo environment. In particular 3-D culture systems using human tissue are thought that they might be a better tool for drug screening by providing more accurate in vivo like structure and organization than 2-D systems and in addition providing some additional information to better inform drug efficacy testing in human—in animal models by prioritizing the drugs that one might want to test first.

Under this topic, the essential features of the system that you would develop are intended to include multi-cellular architecture that represent physiological relevant characteristics. The system should have the ability to examine multiple aspects of cancer such as tumor growth and angiogenesis and other tumor associated properties. The system should also be compatible with high content screening platforms to include multiple molecular readouts such as proteomic, metabolonic or epigenomic analysis.

Again, under the phase one activities and deliverables, offerers are expected to validate their 3-D culture system by showing that it mimics the tumor micro environment and then conduct appropriate preclinical or chemo sensitivity assays to screen response to therapeutics with known efficacious and the plan to specify the metrics in criteria for prediction of clinical efficacy and then go on, again, to demonstrate that accurate prediction of clinical efficacy for drugs with known properties.

Ultimately, there's an expectation in phase one that the newly designed 3-D system would be bench marked against the performance of other currently available 2-D and 3-D culture systems hopefully showing superiority of the new system.

Topic 329 is entitled generation of site—I'm sorry is entitled proteomic analysis of single cell isolated from solid tumors and so this topic is intended to address the challenge that isolating single tumor cells and mapping the single cell protein are critical to being able to understand the chance diseases process, the molecular system levels. The budget I would highlight for this particular topic is substantially lower than the other topics. The phase one budget is listed at $160,000 and phase two is at $1 million. Os make sure you carefully check the budget limitations for each of the topics.

Again, the goal of this really is to advance the field of single cell proteomics through the optimization of single sell isolation from tumors and then to validate and benchmark the system with other proteomic analytical methods. Phase one and activities—phase one activities and deliverable include building the cell isolation prototype and demonstrating proof of concept, functionality of the system using solid tumor examples for proteomic analysis an application and the establishing a protocol to integrate the single cell isolation techniques into the proteomic platform such as a mass spec platform.

Phase two deliverables then would involve demonstrating medium to high throughput isolation capacity of the system and then again, benchmarking the system by comparing it's

performance in contrasting the competitive advantage against other proteomic and profiling methods.

The last topic that I will tell you about is topic 330 entitled generation of site specific phosphotrines protein standards for use in cancer assays. So it's then well recognized that phosphorolated proteins play an important role in the normal and abnormal cellular function and so there's a critical need to produce pure and analytically characterized phosphorescent and polypeptides that one can use as standards in assays that are used to capture the hospitalization signatures of different cancers.

This topic under phase one activities and deliverable has the expectation that you would've proof of concept methodology to reliably produce specifically three immune site directed polypeptide standards for at least two NCI approved cancer targets. I would direct these to the RFP for a specific list of those targets. There are some usual suspects, mentor and AK2 for example, but you can see the full list in the RFP. Here when we say high content that means that there is a target achieving at least 50% phosophorolation of the desired phosophmodified residue and the standard that's going to be produced.

Other phase one is also expected that you demonstrate reproducibility and accuracy of the methodology and then demonstrate preliminary product stability before considering optimizing the process in phase two, working towards improving up to 80% phosphorolation of the desired phospho residues.

I will stop there and turn it over to Deepa Narayanan who goes through the three remaining topics.

Deepa Narayanan: Hello. I'm going to go through the remaining topics that we have. Topic 331 is development of bio cancer chemo biopsy device. The goal of this topic is to develop technologies that are able to incorporate biosensor technologies and biopsy needles and to use this to increase the possibility of sampling high tumor content areas.

Their goal is that this would be used in conjunction with current technologies and current biopsy devices and this would be able to provide real time feedback to the physician providing the biopsy. These bio sensors could be used to detect any physiological or morphology in the biopsy region. These could be PH, elasticity, oxygen content, or dialectic properties. In fact, anything that could direct the physician to select the right tissue to be sampled or excised. We do accept fast track for this contract topic. For the phase one we except to see a prototype device manufactured that can be used with existing imaging, methods and biopsy procedures. Also there should be tests to validate if it does measure can indicate defenses between tumor and non-tumor, benign and malignant tumors, or even necrotic and viable tumor and it should be done in relevant animal models. For a phase two essentially the prototypes should be further defined to be able to be used in a clinical setting.

The next topic 332 is the development of radiation modular use therapy. This topic has been solicited for a couple of years now and we're essentially looking for small businesses they are developing radio sensitizers to enhance tumor killing or radio protectors or radio mitigators that can detector reduce damage during radiation.

One key factor that we want to see is selectivity and by that I mean that if you're develop a desensitization than we want some data or plans to get that data that you compound does not significantly sensitive normal cells and tissues.

Similarly for radio protectors and administrators you need to show data or have a plan to get the data to show that cancer cells are not protected. We will accept fast tracks for this

contract topic. I also wanted to add that for fast track contract topics whether this is for this topic or for any other topic, the phase one must include some technical work, administrative work done in preparation for a phase two will not be acceptable in a phase one.

And I'm not going to go through all of the expected deliverable, but please make sure that there is statistical allocator nor all the proposed study end points. This topic was also amended recently for the phase one, there has been an addition to the activities and expected deliverables, depending on where you are in the compounds and developmental pipeline you need to perform some high throughput studies and so I will ask you to look at the solicitation on our website for the updated topic.

Next topic, topic 333, the goal of this topic is a software tool for the development of environmental measures related to cancer is to develop an efficient user centered software that can connect to different data sources and aggregate and explore the data and use the data for creating metrics that describe the environment or induces related to health, behavior and services. For example, this type of environmental metrics could be used for making policy decisions for cancer prevention programs to bring our geographic locales of new clinics and so on.

Fast track proposals will be accepted. For phase one, we would like to see that you have collected the right tool for this project with the right product matter and environmental data that you are collecting and at the end of phase one we want to have a functional prototype system that can connect to the data sources and then import or export data from these sources and use the right geographic to identify as compatible with our native VIS software and the software can be demonstrated to an NCI evaluation panel.

The phase two activities and deliverable are listed there and I don't think there's anything else that I want to add.

Jennifer: Okay. This is Jennifer again, if you have specific questions about any of those topics, you should summit those questions to Betty at eshanahan@mail.nih.gov. And so we're moving on to the Q&A and again please submit your questions through the Q&A box and we have quite a few so I'm sorry if we don' get to your question specifically but we will try to get to as many as we can.

So the first some of the general questions that came in, for example, can I submit a phase two proposal directly? Who would like to—the answer is no. We don't have that capability. There is there may be some grant funding solicitations, pilot grant solicitations that will be coming out and you'll be able to submit phase two applications directly but they are not yet out on the street so no grants or contacts can be submitted to phase two directly. A similar question. If I apply for a phase one if I am a phase grant recipient, may I apply for a phase two contract.

Betty: This is Betty. The answer is no. You have to be successful receipt of a reward for a phase one contract and perform that effort in order to be eligible to compete for a phase two contract award.

Jennifer: But the converse, if you are a phase one contract awardee, you can apply for a phase two grant.

Betty: Yes.

Jennifer: Another question is can I submit the same project as a proposal for a project and a grant.

Betty: No. You may not. What has happened in the past is we've had people do that and there's a screening process and you will be required to either withdraw your contract proposal or your grant application, but both of them will not be reviewed.

Jennifer: And one kind of followup is if once you've received notice that your contract proposal is no longer being considered for award, then you can submit a grant application.

Betty: Right.

Jennifer: Another question about budget and coming back to staying within the budget amount that's specified under each topic, do you have to?

Betty: No. You don't have to, but it will impact—you're in a competitive environment. So it's—you want to out price your proposal from everybody else that has submitted a proposal then you're endangering your possibility of getting an award.

Michael: Recommendation. Stay within the—

Betty: You should stay within the budget specified.

Jennifer: There were a few questions kind of about the specifics in the application preparation of a contract versus a grant in terms of amount of detail and the proposal structure and page limits and required segments and my advice for that would be to read the solicitation carefully so the solicitation describes the different sections that are required.

Betty: There are very specific instructions and you have to read—and there are different requirements for phase one, proposal, different requirement for a phase two proposal. You have to read the specific directions on how to submit your proposal.

Jennifer: And part of the proposal for is describing the commercial plan. Is there a commercialization plan a difference in how you would like your commercialization plan for contact versus a grant. Anyone want to take that?

Michael: I think it's true for phase one and for phase one contracts if you look at the review criteria it's typically broken out on our expectation that you describe the commercial potential and the commercial applications that are the technology that should develop. So there is probably a bit more emphasis put on the commercial potential of a phase one contract than there is for a phase one grant application. You are expected to address that as part of your application. For phase two contract or grant application I think that the requirements would probably be pretty similar in terms of what is expected.

Jennifer: We have a question about funds to be used in participation of training programs to evaluate your market potential? So there's answer here is generally no. That the budget that's

specified is for R&D activities, but something new with the authorization is that for both grants and contracts you can request up to $5,000 for technical assistance which could be used to for example for market analysis or for hiring commercialization assistance.

Todd: That is the only thing that is not counted in your total budget in terms of both caps, so when we say a total bidet cap of $225,000 that includes direct, indirect and what we call the fee but the only thing outside of that is that $5,000 that you request for technical assistance.

Jennifer: For both grants and contracts you can request up to $5,000 for technical assistance not the regular budget cap but all of the budget should be towards R&D activities.

Deepa: And you can only participate in you can use the money to do your own technical assessment program or you can participate in the NIH commercialization program. You cannot do both.

Jennifer: So we had a couple of questions about the bridge program the bridge award, one is ow much of a phase two grant must be completed before applying for bridge funding?

Andy: So there's no strict requirement with respect to that exact question but for each of the funding announcements that come out we stipulate that your project must have ended bore a certain date in order to be eligible under that RFA. So for example we intends to issue a new funding announcement within the next couple of months. Those applications, bridge applications if they funded would be supported before the end of the current fiscal year which would be September 2014. So your phase two project if you want to apply under that announcement would need to end before August 31 of 2014 in order to be funded in the current fiscal year.

I think the other consideration is obviously to wait to apply until you have a sufficient amount compelling data so in addition to the timing requirement that we put on it, obviously you would want to make sure that most of your aims of the phase two had been successfully accomplished since that is one of the review criteria they we look at is how productive unsuccessful were you during phase two.

Jennifer: And then must outside funding be in place before you apply for bridge funding?

Andy: Yes. So this is a common question and what we expect at the time of application that you present a compelling plan for raising matching funds that will match the bridge award for the entire project period so if that's three years we would expect you to present a plan for raising matching dollars for over a three year period. We don't expect you to have all of that money secured and in the bank at the time you applied, before we would make anew award we would expect that you had at least the first year's worth of funding from your private investors closed and in the bank before we would initiative the first year of NCI funding and have the same expectation in future years, so you cantors of stage the fund raising. If it's tied to particular triggers or milestones that your investors have stipulated, we would ask that you would describe what those triggers are so that you can understand whether your key milestones in the project line up with what your investors will be expecting.

Certainly every deal is a little bit different that we found with the bridge program so I would definitely encourage anyone considering a bridge application to give us a call and we can talk about the specifics of what we're thinking about.

Jennifer: Going back to contracts, and then I have some more general questions and then we have a couple of topic specifications that we may be able to answer, so one comment is that and I'm not sure if this person is referring to a specific topics, but the milestones seem extreme ambitious for this amount of money. Are all the milestones expected to be met?

Betty: I would have to say yes. It would be helpful to know the specific topic they were referring to.

Andy: I think for questions like this. We would request that you send an inquiry to Betty and we can address specifics offline.

Jennifer: I've got another general question, does the fact that the contract is solicited for a particular topic boost the NCI for programmatic interest in that topic when applying for a grant.

Andy: The answer is possibly and very often, but again it's topic specific. As Michael described, we go through a fairly involved process of trying to identify the overlap between our interest in technology development and where we see key commercial opportunistic and develop those contract topics around those areas where there is intersection. We can't possibly envision all of the commercial opportunities that exist nor all of the potential features that they could be designed or thought of or received, so I think Michael said something important alone the was which was not to chase solicitations. I think if you see a contract topic that sort of overlaps with some of your core competencies but isn't what you had envisioned as a final product then it's worth having a call with the program director to sort of flesh that out to see if there's an opportunity to submit a grant.

Jennifer: I'm going to see if you'd like to answer some of these topic specific questions. For topic 227, sorry—327 which is the reformulation topic, does the formulation technology have to be innovative or is a novel and innovative drug formulated with a sophisticated but established formulation technology sufficient?

Andy: The answer is yes. What you described would be considered responsive provided that the small molecular therapeutic has not received approval FDA approval for any indication. I think some of this will be discussed during review, so the novelty of the delivery platform will be something that will be considered, so bear that in mind, you know when it comes to considerations like competitive advantage. Again, we would prefer that specific questions like this go to Betty so that we can address those off line and discuss more of the details of your specific questions.

Jennifer: For topic 332 is it necessary to have in vivo toxicity studies feeling that it's not the radio modulator is not sensitized to healthy cells.

Deepa: It's not necessary. But if you don't have the data you should have some experiments to show that it's one.

Jennifer: A question about scoring. So what is a—we're going back to general questions again, what is a promising score for contract or for grants, discussing the review process and you get a score back, what's promising?

Andy: I'll address the grants question first. NCI has taken somewhat of a uniform process for grant funding selections which involve establishing what we call a zone of probable funding which is a very conservative funding range or conservative cut off for which applications that score t that cutoff or better are extremely likely to get funded unless there is some issue or administrative problem that would prevent us from funding that. I think in recent past about 60% or so of our SBIR grants have fallen within that very competitive range. Above that range we go through a process where we go grant by grant and look very carefully at the outcome of the review and make sure that nothing was missed. We consider things like programmatic balance and we discuss all those things in the context of our overall portfolio and mission and balance and last year for grants a score of 28 or better was 90+% of those grants were funded. About 50% of the grants that scored between 29-36 were funded and it fell off very quickly after 36. I think we might have funded one grant above 36. So those ranges vary from year to year depending on the number and the quality of applications they to get in the door but that gives you a sense of the process that we go through.

For contracts, contracts are scored on a different scale from 0-1000 being the best score. I think it really depends on the contract topic what would be a competitive score. I think it is fair to say things that are in the 800-900 range are quiet competitive. Sometimes a 600 or a 700 could be competitive. Sometimes not. Again, it depends on what the distribution of scores was, how many proposal have money to fund and the distribution of different technologies in that particular round. That gives you hopefully some sense.

Betty: This is Betty. Also there are other factors than score when it comes to the contracts, the scoring and then the project officer makes a recommendation to us based on the interest of the institute and the technology, the priorities, and the amount of money that is available under the topics. So there are other factors. It's not like grants where we fund a percentage of proposals that are received or there is a cutoff on the scoring. There are lots of different factors that are to be considered.

Jennifer: So coming up on the wrapping up, I will be sending, opening up a poll so we would appreciate it if you wanted to give us feedback. Please feel free to contact us at NCISBIR@mail.nih.gov. And sign up for the mailing list for any updates to new funding solicitations.

Yes, so the poll should be up on your screen, please feel free to give us some feedback about this webinar and we will be posting the slides. We will send the amount to all of you who are on the call. We also plan to post answers to some of the questions that we received and we know that we didn't get to everybody's question so we will talk about how best to get back to you but if you have specific questions that weren't answered, if it's about a contact topic, please e-mail Betty at eshanahan@mail.nih.gov. If it's a grants related topic or question or a general

question about the NCI SBIR STTR program please contact NCISBIR@mail.nih.gov. Does anybody else have any last—

Michael Weingarten: Just a reminder that the deadline for contract proposals to be received is November the 25th at 4:30 and again we need to actually have your paper application in hand on that date.

So you know that's just over six weeks away and if you see a good match there then strongly consider applying for that and give any questions you might have to Betty and we can follow up.

Jennifer: Thank you.